EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

Master File No. 2:12-MD-02327 MDL 2327

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

CONSOLIDATED TRIAL

MULLINS, ET AL. JOSEPH R. GOODWIN

v. ETHICON, INC., ET AL. U.S. DISTRICT JUDGE

CASE NO. 2:12-cv-02952

Baltimore, Maryland
Thursday, July 14, 2016

General TVT Deposition of:
HARRY W. JOHNSON, JR., M.D.
the witness, was called for examination by counsel for the Plaintiff, pursuant to notice, commencing at 8:22 a.m., at the Kimpton Hotel Monaco Baltimore Inner Harbor, 2 North Charles Street, Baltimore, Maryland 21201, before a Notary Public in and for the State of Maryland, when were present on behalf of the respective parties:

A P P E A R A N C E S

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C O N T E N T S

E X H I B I T S

P R O C E E D I N G S

Whereupon,

HARRY W. JOHNSON, JR., M.D.

a Witness, called for examination by counsel for the Plaintiffs, having first been duly sworn, was examined and testified as follows:

EXAMINATION BY COUNSEL FOR PLAINTIFFS

BY MR. CRONE:

Q. Dr. Johnson, I know we've met, but if you could state and spell your name for the record, please.

A. Harry Wallace Johnson, Jr. That's H-a-r-r-y, Wallace, W-a-l-l-a-c-e, Johnson, J-o-h-n-s-o-n, Jr., J-r.

Q. And you've had your deposition taken before?

A. I have.

Q. Okay. So it's fair to say you understand the ground rules generally?

A. Yes.

Q. Okay. The only thing I'll repeat, then, is that when I ask a question, if you don't understand it, please ask me to clarify. I have no interest in you answering questions you don't understand, but if you don't ask to clarify, I'll

assume you understood the question. Fair enough?

A. Yes.

Q. Okay. Good.

So, Dr. Johnson, you've been retained by the Defendants to offer a general causation opinion on the TVT product; is that correct?

A. That's correct.

Q. And you've drafted an expert report expressing those opinions?

A. That's correct.

Q. Okay. And that expert report expresses opinions on the TVT product?

A. That's correct.

Q. And on the TVT-O product?

A. Yes.

Q. Okay. Would you agree that the Mullins consolidation involves cases only regarding the TVT product?

MR. COMBS: Dr. Johnson may not know that. I'll stipulate that it does, but you're welcome to ask him about it.

MR. CRONE: Yeah.

BY MR. CRONE:

Q. I mean, do you know that, Dr. Johnson?

A. That's my understanding.

Q. Okay. And so would you agree, then, that any opinions in your general causation report related to the TVT-O product aren't relevant to this -- to the Mullins consolidation litigation?

A. Well, some of my opinions for -- would apply to either product.

Q. Okay. Yeah, let me ask it a bit more clear.

Do you intend to offer any opinions on the TVT-O's safety?

MR. COMBS: Object to form.

THE WITNESS: Well, I would say when I came to this deposition, I thought we were talking about TVT. If asked questions about TVT-O, I would answer those questions. Is that what you mean?

BY MR. CRONE:

Q. Well, yeah, I also thought we were talking about TVT only. I'm referring to the opinions expressed in your report relating to the TVT-O.

So the question I'm asking is: Are you intending to offer opinions at any future date on the TVT-O product's safety?

MR. COMBS: Object to form.

THE WITNESS: I'm not sure I completely understand, but what I think you're asking me, if

I'm going to offer opinions about TVT-O in these six cases.

BY MR. CRONE:

Q. That's correct.

A. I'm going to offer opinions about TVT in these six cases.

Q. Okay. So in these six cases, you won't offer any opinions related to TVT-O's safety or efficacy?

A. Only if a question about TVT-O were to come up.

Q. That's fair enough.

So, Doctor, I'm going to hand you some exhibits. And these are out of order. And believe it or not, last night I reordered this to try to be more efficient. So I'm going to mark them out of order, and the first exhibit is your reliance list.

MR. CRONE: If we could mark this as Exhibit 4.

(Exhibit 4 was marked for identification and is attached to the transcript.)

BY MR. CRONE:

Q. And then I will hand you your supplemental reliance list.

MR. CRONE: And this we'll mark as

Exhibit 5.

(Exhibit 5 was marked for identification and is attached to the transcript.)

BY MR. CRONE:

Q. Okay. So have you seen these two documents in front of you, Exhibit 4 and 5?

A. Yes.

Q. Okay. And what are these?

A. It's a reliance list and a supplemental reliance list.

Q. Okay. And so are all of the materials listed in the reliance list and supplemental reliance list materials you relied on in forming your opinions on the TVT product?

A. The materials that I relied on are within this list.

Q. Okay. And so there are additional materials on the list that you did not rely on?

A. No. There's -- there are things in this list that I didn't review that I didn't feel were important to me.

Q. Okay. And so the materials on the list were provided to you by Ethicon's attorneys?

A. By Butler Snow.

Q. Okay. And Butler Snow is the law firm --

one of the law firms that represents the Defendants, correct?

A. Yes.

Q. And so they sent over various materials for you to review?

A. I mean, my understanding is they sent everything on these reliance lists.

Q. And then you reviewed some of it, relied on that to form your opinions; is that fair?

A. Yes.

Q. And then some of it you didn't review because you didn't think it was relevant or necessary?

A. Yes.

Q. Okay. And so what is your understanding of -- how would you define a reliance list?

MR. COMBS: Objection to the form. Asks for a legal conclusion from a lay witness.

THE WITNESS: It would be materials that I can review and rely on to help me write a report and reference medical literature involving the report that I would be writing.

BY MR. CRONE:

Q. Okay. And so why, then, did you include information on the reliance list that you didn't, in

fact, rely on in forming your opinions on the TVT product?

MR. COMBS: Objection to form.

THE WITNESS: Well, this list is a list of everything that I was sent, so I just provided a complete list of materials that I was sent.

BY MR. CRONE:

Q. But these aren't, in fact -- there are many materials on the list that you did not rely on in forming your opinions on the TVT product; is that fair?

A. Well, there's a lot of things in this reliance list that are referenced in other articles on the reliance list, so it's kind of intermingled.

Q. Okay. So is it possible -- would it be possible for you, then, to go through Exhibit 4 and 5, the reliance list and supplemental reliance list, and pare it down to the -- just the materials you actually did rely upon in forming your opinions on the TVT?

A. Well, I don't think that would be possible because a lot of this material I reviewed and just formed opinions over a long period of time, not specifically for this report. So I reviewed literature in addition to performing the report

that's part of this literature --

Q. But you would --

A. -- or medical science.

Q. But you would recognize any materials on there you haven't ever read before, correct?

A. For the most part, yes.

Q. All right. We'll set those aside.

I'm going to hand you what we'll mark as Exhibit 1 now.

(Exhibit 1 was marked for identification and is attached to the transcript.)

BY MR. CRONE:

Q. So Exhibit 1 is titled Notice to Take Deposition of Dr. Harry Johnson, Jr. Have you seen this document before?

A. I have seen this.

Q. Okay. And you've reviewed it?

A. Yes.

Q. Okay. And this document asked you to bring various documents with you? To help you out here, it's at page 6. It starts at page 6 of the document and then goes to the end. It asks you to bring various documents. Do you see that?

A. Yes.

Q. Did you bring those documents?

A. I brought my general report and a literature book.

Q. Okay.

MR. COMBS: And then I have also brought a thumb drive, which is marked Johnson General, which, it's my understanding, would have an electronic copy of the materials on Dr. Johnson's reliance list.

BY MR. CRONE:

Q. So the thumb drive has the reliance list materials. You've brought the general report.

A. Yes.

Q. Anything else?

A. I brought a book of TVT medical literature.

MR. CRONE: Which would be on the thumb drive, right, Phil?

MR. COMBS: It should be. I mean, I'm always hesitant to answer that because I don't actually make the thumb drives, but if there is anything in that medical literature notebook that is not on the thumb drive, that is an error.

MR. CRONE: Okay.

MR. COMBS: It should have everything that is in the TVT medical literature book and everything that is in the notebook that's in Dr. Johnson's left

hand.

MR. CRONE: Okay. Great.

BY MR. CRONE:

Q. And did you bring any invoices for work completed thus far?

A. I did not.

Q. Okay. Have you generated any invoices?

A. I have not.

Q. Why is that?

A. Well, probably the simplest answer is I've been working to get ready for this. So I'll prepare one afterwards. I'm happy to share that with you.

Q. Yeah, that would be great. At a later date would be fine.

This ties into it, so I'll just mark this now. As you know, we have a copy of your CV. And I think it's just slightly out of date.

MR. CRONE: We'll mark this as Exhibit 3.

(Exhibit 3 was marked for identification and is attached to the transcript.)

BY MR. CRONE:

Q. And while we're at it, let's get your general report in this matter marked, which is Exhibit 2.

(Exhibit 2 was marked for identification

and is attached to the transcript.)

BY MR. CRONE:

Q. Okay. So, Doctor, if we can go to page 3 of Exhibit 2, which is your expert report. It's the one just handed to you, Exhibit 2.

MR. COMBS: John, you said page 3?

MR. CRONE: Page 3, yeah.

MR. COMBS: Okay. Thank you.

BY MR. CRONE:

Q. In the middle of the page, it lists your rates there. Are those rates current?

A. Yes.

Q. So is it your practice, then, to bill -- to -- I'll use the term line item bill, if you understand that, when you send an invoice, or how do you generate your invoices?

A. Just like this summary here.

Q. So one line might have a summary indicating you met with somebody or had a telephone call and you would just note the amount of time that took?

A. Yes.

Q. Okay.

MR. COMBS: John?

MR. CRONE: Yes.

MR. COMBS: Just before you leave this page --

MR. CRONE: Sure.

MR. COMBS: -- I want to say something about it, but I don't want to interrupt you.

MR. CRONE: Oh, no. Please go ahead.

MR. COMBS: Well, I just wanted to say, I look at this and I notice an error on page 3 in terms of it listing Dr. Johnson's testimony. Because in 2014, Dr. Johnson did give a deposition, which, you know, obviously the Plaintiffs are familiar with because you have it, but it's in the Huskey/Edwards case. So it's just an error on that list.

MR. CRONE: Okay. Yeah, and I was going to get to that, but we might as well clear it up now.

BY MR. CRONE:

Q. So you recall giving a deposition in the Huskey/Edwards v. Ethicon case?

A. I do.

Q. Okay. And when you gave that deposition, you testified accurately in that deposition?

A. To the best of my ability.

Q. Truthfully to the best of your ability?

A. Yes.

Q. And so that is an error and should be included in the expert report on that list on page 3?

A. Yes. I don't -- I don't actually keep a list of cases, but I went through, to the best of my ability, my calendar to generate this list. So I must have missed that. I don't --

Q. Okay.

A. It was unintentional.

Q. And do you think with that addition it's complete now, that list?

A. I believe I gave one deposition in the last month not related to this matter that's not listed here.

Q. Okay. And what sort of matter was that?

A. That was a malpractice case.

Q. Do you know the name of the case?

A. I don't know the name, but I'm happy to provide that to you.

Q. Sure.

Dr. Johnson, have you ever acted as a consultant for any matter for Ethicon?

A. With regard to what? I mean, I prepared the -- I prepared the general report we just

discussed in the Edwards matter.

Q. No. I'm referring to things like preceptorships, proctorships, consulting on -- I mean as broad as possible -- consulting on drafting IFUs, patient brochures, that sort of thing.

A. I did on several occasions work as a preceptor. In other words, Ethicon brought in two or three surgeons to watch me perform a TVT. I was a faculty member in courses for a company named IMET, I-M-E-T, that I believe -- well, the company taught all different types of surgical procedures, if you will, and TVT was, I believe, taught in that course. And some of the courses may have been sponsored by Ethicon. I was just a faculty member in the course but not -- I don't believe that we were -- I wasn't working for Ethicon at the time. I was teaching a course for the IMET company.

Q. Okay. So excluding the IMET company work and -- so then acting as a preceptor for Ethicon prior to that, anything else that you did for Ethicon?

A. No. I was never -- I never contracted with Ethicon to do any sort of teaching in these procedures. I just agreed a time or two for observation of cases that I was doing.

Q. And when did you conduct these activities?
A. That was in the early 2000s. I don't know. Early to mid 2000s.
Q. Would it be as late as 2008?
A. I don't believe so.
Q. So if there were a document out there showing that you did work for Ethicon in 2008, would that be -- would that document be inaccurate?
A. I -- I mean, I suppose it's possible I did something in 2008. I would have to look at the document. I don't recall the specific dates. I just know that I didn't do this very much. But it was sometime -- I mean, when I did it, it was sometime between -- sometime prior to 2010, I'm sure, fairly sure, but I don't recall the dates exactly.
Q. Can you estimate the total amount Ethicon has paid you for all of your consulting activities? Is it fair if I just call them consulting activities?
MR. COMBS: Just so that I understand, are we talking about as a preceptor?
BY MR. CRONE:
Q. Yeah, we're talking about as a preceptor and then anything else -- I know you're having a

hard time remembering exactly what you may have done and when, but certainly if I use the term "consulting activities," I'm including as a preceptor and anything else you may have done.

MR. COMBS: But -- here's the only thing I want to understand. Are you talking consulting work and the medicolegal work?

MR. CRONE: No. No. I'm sorry.

MR. COMBS: Okay. That's the part --

MR. CRONE: Okay. That's a fair question. I understand.

BY MR. CRONE:

Q. Not anything related to your retention as an expert.

A. Okay.

Q. So not drafting expert reports or anything like that. Just this prior consulting work that you discussed in the 2000s, maybe as late as -- you know, prior to 2010, that work that you described. Can you estimate how much you were paid for all of that?

A. I'm not sure that I can give you a real accurate estimate, but I would say, if I -- if I made some sort of guess --

Q. Sure.

A. -- without reviewing any sort of historical documents or anything, I would think it would be less than 5- or $10,000. I just don't recall exactly what I did.

Q. You don't think it could be more than $20,000?

A. I would seriously doubt that.

Q. Okay. So let's go back to your expert report that's Exhibit 2. I think you already have it in front of you. Ethicon -- or the attorneys for Ethicon, I should say, asked you to write this opinion; is that correct?

A. Yes.

Q. And let's look at page 2. If you look at the second full -- the second full paragraph from the bottom of the page, it starts with: "I am a very active surgeon."

A. Yes.

Q. The next sentence says you've performed at least 750 polypropylene midurethral slings. Is that an accurate number?

A. Fairly accurate.

Q. And you're still performing about 50 sling procedures per year?

A. Maybe a little less in the last year or

two.

Q. And why have you been performing a bit less?

A. Well, I have some more administrative duties, and I had took some time off for a surgical procedure, so it changed --

Q. And then --

A. -- my practice a little bit.

Q. I'm sorry. I didn't mean to interrupt.

A. That's okay.

Q. The last sentence in that paragraph says you currently use the TVT-O and TVT-Exact. Why is that?

A. Well, I use what we have at our hospital. So the TVT and the TVT-Exact are essentially the same product, so I use them interchangeably. Actually, I still use the regular TVT.

Q. How often do you still use the regular TVT?

A. Well, I operate at four different hospitals and not everybody has the Exact. So I would guess it varies from year to year depending where I'm operating. I don't know if I can give you an exact number. It just varies from year to year.

Q. That's fine. No need to guess.

If a hospital has the TVT-Exact and the TVT, do you prefer the TVT-Exact?

A. I really don't have a preference. The difference of the needle is minimal or the passer.

Q. What sort of mesh is in the TVT?

A. Polypropylene Type I Macroporous mesh.

Q. And is that the same type of mesh that's in the TVT-Exact?

A. They're both -- they're both polypropylene mesh.

Q. Do you know if the TVT-Exact polypropylene mesh is Type I Macroporous?

A. I believe it is.

Q. Okay. Moving ahead to page 3. The first full paragraph, the sentence starts with: "The UITN Network."

Do you see that sentence?

A. Yes.

Q. And it mentions in that same paragraph that the UITN Network conducted a large, prospective, randomized surgical trial -- or trials. And what -- starting with the first one because -- well, first let me ask: When you say "trials," you mean they conducted more than one study?

A. That's correct.

Q. Okay. And so when was the first one conducted?

A. It started sometime around the early 2000s.

Q. Okay. And were those studies -- or trials. I'm sorry. Were those trials looking at the TVT product?

A. Initially we looked at Burch versus fascial sling.

Q. Okay. Then skipping ahead to the next trial, then, which products did that -- or procedures did that look at?

A. TVT, TVT-O, and Monarc. It was looking at retropubic versus obturator. And obturator used two different -- there was two different slings that were used in the obturator arm that were based on surgeon preference.

Q. And the TVT uses the retropubic procedure, correct?

A. That's correct.

Q. Let's skip over to your CV, which is Exhibit 3. And I understand this is just a bit out of date, so let's skip to what we know is a bit out of date.

On page 2, under specialty boards,

Diplomate, American Board of OB/GYN, the recertification stops at 2013. Were you then recertified in 2014, 2015, and 2016?

A. Yeah, I'm currently recertified. In 2014, I missed the deadline for a test so I had to file for a re-entry test, which I took and passed, to put me back on the yearly schedule.

Q. And you're unaware if during that time you missed a test and then filed the paperwork for the re-entry test the certification lapsed in that period?

A. I'm not sure on that. The test was due by December 31st, and I completed it, I think, around the beginning of April. So the March-April time frame.

Q. Okay. Skipping to page 5.

A. The --

Q. Oh, I'm sorry. Go ahead.

A. The one thing I would say in the specialty boards that's not there, also in -- I was certified in female pelvic medicine and reconstructive surgery last year, which is a subspecialty certification within the board of OB/GYN.

Q. Okay. And how does that differ from the prior certifications?

A. The OB/GYN certification is for general OB/GYN. It's an examination that you take after you complete your residency followed by an oral examination. And then the recertification is a yearly -- you have a choice of recertification every seven years or ten years depending on when your first certification was or you can choose the yearly certification. In 2000, the yearly certification started, and you can choose that by choice.

In 2013, the board developed a subspecialty certification in female pelvic medicine and reconstructive surgery for people that had either extensive experience or fellowship training in pelvic floor issues. And they had a -- offered an examination for subspecialty certification starting in 2013. And now that's the certification that people would take in addition to their OB/GYN certification as a subspecialist.

In OB/GYN, there are four subspecialties, and this is the latest and fourth one that was added. There's maternal-fetal medicine, reproductive endocrinology, oncology, and now female pelvic medicine and reconstructive surgery.

Q. Okay. And the female pelvic medicine and reconstructive surgery certification, that would

relate to performing procedures to repair incontinence?

A. That's one of the things that it refers to.

Q. It would also refer to prolapse repairs and other things of that nature?

A. Basically things that affect the pelvic floor function of the bladder, vagina, bowels, rectum-type thing, and surgical procedures therein, evaluation, treatment, that type of thing.

Q. Okay. So let's skip to page 5. Under research grant, do you see the first one listed there talks about the UITN grant? And who provided that grant money?

A. The National Institute of Health.

Q. Was it all from the National Institute of Health, all of the grant money?

A. That's my understanding, yes.

Q. Okay. On page 6 -- let's skip to page 6, Doctor. Well, no need.

On page 7, at the bottom, there's a column -- or excuse me -- a heading listed invited speeches, presentations. The first one begins in -- that's listed is 1994. The last one listed, on page 9, is in 2001. Is this list up to date?

A. Probably not. This is from 2014.

Q. Okay. How many additional presentations or speeches do you think you've given that aren't on this list?

A. I don't think there's very many, but I'm happy to provide you with an updated CV.

Q. That would be great. Thanks.

Okay. Let's go to page 4 of your expert report, and that's Exhibit 2. Okay. The very first sentence at the top of page 4 reads: "Urinary incontinence affects up to 50 percent of women with range of 10 to 70 percent."

What does that mean?

A. That means that a lot of women leak urine on average.

Q. So up to 50 percent of women suffer from leakage?

MR. COMBS: Object to form.

THE WITNESS: Well, that's a -- what I was talking about there is there's an average. So 50 percent would be an average, but the range may be 10 to 70 percent. I think it -- I might understand the semantics you're asking me. If it affects up to 50 percent, how can the range be 10 to 70 percent?

BY MR. CRONE:

Q. Well, I think I understand now. I think you're saying that the average is 50 percent, correct, but the range could be 10 -- as low as 10 up to 70? Is that fair?

A. Yeah. There's a lot of different numbers reported in the literature and this is kind of an average. That was my meaning here.

Q. Okay. I understand.

When thinking about trials or studies -- so this question will apply to both. It's compound, I understand that. We'll take it one at a time.

Would you agree that the results of any given -- let's just say study first -- may vary wildly based on methodology, just as a general proposition?

A. I agree there can be variability based on methodology.

Q. And would you agree to that same general proposition with regard to trials?

A. Yes.

Q. And the third full paragraph on page 4, at the second-to-last sentence of that, it starts with: "Urinary incontinence is a prevalent condition with significant medical, social, and psychological

ramifications."

Do you see that sentence?

A. Yes.

Q. And then the next sentence says: "It is a symptom and not a diagnosis and is seen in all age groups."

What do you mean by it is a symptom and not a diagnosis?

A. Well, there's a lot of different things that can cause urinary incontinence. So the symptom is leakage, but the cause is not the leakage. A lot of different medical conditions can cause leakage, if you will.

Q. Can you give just one example of that?

A. Well, I mean, let's say you have a dementia patient that can't control her bladder. She has urinary incontinence.

Q. So in your view, then, the patient suffers from dementia and a symptom of that dementia is urinary incontinence?

A. In that case, yes.

Q. Are there cases where urinary incontinence is a diagnosis in and of itself?

A. Well, there's different types of urinary incontinence. So there can be -- for example, a

fistula or a hole in the bladder can cause incontinence. You can have a bladder that doesn't work where the patient has overflow incontinence; or you can have stress incontinence, which is leakage with an increasing intraabdominal pressure or non-function of the urethral sphincter; or you can have urge incontinence which can be neurologically based where the bladder is -- a common term is overactive bladder where the muscle contracts and urine is released without the patient wanting to release urine, in other words, incontinence instead of voiding.

Q. Okay. So, Doctor, I think I understand. So in those instances -- let's take the fistula, for example. The fistula is the cause and the stress urinary -- or the incontinence is the symptom of the fistula?

A. Exactly.

Q. Okay. Skipping to page 5, the very last paragraph, second sentence -- this is under a heading that says nonsurgical options. You say: "Up to 50 percent of women may improve enough to forego surgical treatment initially. However, greater than 90 percent of these patients remain incontinent and greater than 60 percent may

subsequently seek surgical management."

Why is that the case?

A. Well, nonsurgical management doesn't always work or it may work and then the patient gets worse and looks for another form of treatment. I think worsening incontinence is a complaint that people often come in with seeking options for treatment and they may move to a surgical treatment.

Q. So a patient with incontinence would likely try a nonsurgical option prior to trying a surgical option?

A. Well, certainly that's one of the options for the patient depending on the type of incontinence. Now, of course you know that a nonsurgical treatment, for example, for a fistula has a low chance to work. So I think you have to be specific about what the problem is to say whether the treatment would work or not.

Q. Sure. Let's take stress urinary incontinence.

A. Okay.

Q. Would a nonsurgical option -- would it be appropriate to first try a nonsurgical option if a patient had SUI?

A. That's certainly an appropriate initial

treatment in addition to a surgical treatment.

Q. Sticking with that example, if a patient had SUI -- and SUI stands for stress urinary incontinence, correct?

A. That's right.

Q. If a patient had SUI and tried a nonsurgical procedure first, do you know what the success rates are for nonsurgical treatments of SUI? And by success rates, I mean both objective and subjective.

A. I would say on average in the literature, at best, it would be 50/50. There is certainly some variability in success. And a lot of it depends on the degree of the problem and also associated conditions with the problem whether that would work or not, and that's why you have a wide range of variability.

Q. Do you know what or which literature supports that opinion, the at best 50/50 success rate opinion?

A. I can't point you to a specific document right off the top of my head.

Q. And let's go to the next page, page 6, and start at the top. The letters A through G there, there you're listing nonsurgical options for SUI; is

that correct?

A. Yes.

Q. And that success rate we just discussed, 50/50 with variability based on severity of the SUI, does that apply to all of these collectively?

A. Well, it's based on variability of the severity of the incontinence as well as associated conditions, so it's difficult to define which ones it would work best in. But I don't believe any of them have a success rate in general over 50 percent.

Q. And if the patient chooses a surgical option, would you agree that the goal, then, is to achieve long-term continence with low rates of complications related to the surgery?

A. That would be optimal.

Q. That would be optimal.

A. Yeah, of course we want to perform procedures that work in the long term to maintain continence.

Q. And so if you performed a procedure that provided the patient with long-term incontinence with low rates of complications, would you consider that procedure to be safe?

MR. COMBS: Object to the form. John, I think you just accidentally misstated the question.

You might just want to rephrase it or restate it.

BY MR. CRONE:

Q. No. I'll clear it up.

A. What I heard was -- instead of continence was a surgical procedure to give you incontinence.

Q. Oh, no. I'm sorry. I understand that's never the goal.

(A discussion was held off the record.)

BY MR. CRONE:

Q. If the procedure produced long-term continence, not incontinence, with low rates of complications, would you consider that procedure to be safe?

A. So a procedure with a low rate of complications is very good. I'm not sure what you mean by safe. All operations carry risk.

Q. Sure, they all carry risk. I'm trying to -- what I'm trying to get at is how you define safety. So let's go back to the question I asked.

You perform an SUI surgical procedure. After that occurs, there's long-term continence, low rates of complications. Would that be an efficacious procedure?

MR. COMBS: Object to form.

THE WITNESS: Again, I'm not exactly sure

what you mean by that.

BY MR. CRONE:

Q. How do you define the term or the word "efficacy"?

A. Well, if the procedure works or not would be my understanding of efficacy.

Q. Okay. And so would a procedure that produces long-term continence be efficacious under your definition?

A. Well, I would like a procedure that gives long-term -- of course the procedure we're doing is for continence, to restore a patient to continence, and the best procedure would be a procedure that provided long-term continence.

Q. And if it did, that would be -- that would signify that the procedure was efficacious?

A. Well, it would signify to me that it's a good procedure that's achieving the result that we are intending to try to obtain.

Q. So now I'll ask the safety question again. How do you define whether or not a procedure is safe, an SUI surgical procedure?

A. All procedures that we perform in stress urinary incontinence that are surgical procedures have known adverse events, whether -- so I don't

know that I -- you know, what I would want is a procedure that has a low incidence of adverse events.

Q. So if a procedure had a high incidence of adverse events, that's not the type of procedure you would want to perform?

A. Well, again, a procedure may have a large number of possible adverse events as a surgical procedure, and I think I would look at each one individually to decide whether -- what I thought about the procedure.

Q. Okay. And adverse events can be reported to the FDA; is that correct?

A. Yes.

Q. Adverse events are studied and compiled in the medical literature; is that correct?

A. Yes.

Q. So with any given SUI procedure -- let's take the TVT procedure specifically. You could look at the TVT procedure, look at the medical literature and determine the -- how many adverse events are associated with that type of procedure; is that correct?

A. I would look at the medical literature, especially meta-analysis-type papers that could

provide me with adverse events that had been reported in the medical literature and how often and what they were.

Q. Sure. And if they -- if there were a great number of adverse events, you would not want to perform the procedure; is that correct?

MR. COMBS: Object to form.

THE WITNESS: No.

BY MR. CRONE:

Q. Okay.

A. That's not correct. I don't know if I'm --

Q. No, I understand. So let's just -- let's be more specific.

If there were adverse events in 5 percent of all TVT procedures performed, would that be too high for you to consider performing the TVT procedure?

A. Well, I think you would look at the -- what the adverse events are and you would compare it to current procedures that are also done for the procedure -- or the other procedures that are done for surgical treatment, say, for the same or similar patient and decide what you thought about the procedure as compared to the current surgical

treatment of that problem.

Q. So what types of adverse events would you look for?

A. Well, I think the best thing for TVT would be to refer you to the Schimpf meta-analysis to look at the different adverse events that can occur or that have been studied in the medical literature and their incidence as compared to other procedures.

Q. Sure, but the question I'm asking is when you're doing this analysis, what types of adverse events do you look for?

MR. COMBS: Object to form.

THE WITNESS: Well, again, in this situation, I would refer to large databases that have looked at large numbers of patients rather than an individual experience. I mean, I can talk about my experience, but it's better -- I think it's much better decision making to look at the current medical literature and compare it with your experience.

BY MR. CRONE:

Q. Okay. And what types of adverse events does the medical literature report with -- just in relation to the TVT product or the TVT procedure?

A. Well, if you look at the Schimpf

meta-analysis, the things that are reported comparing the different types of procedures for surgery for stress urinary incontinence, they report what you could consider -- actually, they report a lot of different adverse events. Some could be considered minor; some could be considered more major.

But the things that they reported in general were urinary tract infection, bowel injury, nerve injury, ureteral injury, vascular injury, overactive bladder, urgency, retention of urine lasting less than six weeks, retention of urine lasting greater than six weeks, return to operating room for urinary retention, groin pain, leg pain, bladder perforation, urethral perforation, vaginal perforation, deep vein thrombosis.

And in that, they compared -- when possible, they compared that to the different procedures that are currently or recently performed for the treatment of stress incontinence, which included procedures with mesh and included procedures that did not use mesh, and they compared the adverse events to each other or looked at the differences or provided the differences.

Q. Okay. In your mind, off of that list you

just gave me, which ones are serious? I think you used the word "serious." If I'm mischaracterizing that, I apologize.

A. Well, I don't mean to downplay any adverse event. Of course anything that happens with a patient we take seriously. But certainly there are things that are more difficult to treat. For example, bowel injury would be a very significant injury.

Q. Okay. Then was it your testimony that there isn't a rate of adverse events with regard to the TVT procedure at which you would say I can no longer perform this procedure generally, it's always a case- or a patient-specific analysis?

MR. COMBS: Object to form.

THE WITNESS: Well, I think generally you would look at a patient. And one of the ways you may decide is depending on associated pathologies or conditions if a procedure in that particular patient -- depending on what other procedures you're doing, is one procedure better than the other. No surgical procedure is without surgical risk.

BY MR. CRONE:

Q. And are there any surgical procedures that are with so much risk that you would never perform

them?

A. Are we talking about with urinary incontinence?

Q. Urinary incontinence, yes.

A. Well, historically there have been over 100 procedures described in the literature for treatment of urinary incontinence. I certainly have not performed 100 different procedures. The procedures that are current I believe are safe and have good outcomes and long-lasting results and are acceptable treatments for patients with stress incontinence.

Q. What's your basis for the opinion that historically there have been 100 procedures to treat SUI?

A. My reading and general understanding of published literature, textbooks, historical perspectives.

Q. Are you familiar with the Monarc --

A. I am.

Q. -- product?

Would you use the Monarc product today?

A. I don't use the Monarc product.

Q. And why is that?

A. Well, first, I was never trained with the

Monarc product. And personally, I like the inside-out procedure. So I just have never used the Monarc. That was part of the TOMUS study. But my choice was not to be trained in that and not use the Monarc.

Q. Okay. Is the Monarc still on the market?

A. I don't use the Monarc, so I'm -- I'm not sure of the answer to that question.

Q. Are you aware of any products that were designed to treat SUI that are -- were introduced to the market and subsequently taken off of the market?

A. I know there are some. I don't know that I could give you a complete list.

Q. Do you know why they were taken off the market?

A. Some of the -- some of the sling materials that were used early on were found not to be good materials, such as Gore-Tex. Some weaves of mesh such as -- one that comes to mind is the ObTape -- were removed from the market for reasons of not working well, more complications.

Q. They were removed for safety reasons, correct?

A. That's my understanding, yes. And I should add some of the biologics were removed as

well.

Q. You mentioned the TOMUS study a minute ago. Can you give a general overview of what the TOMUS study was and what it was designed for?

A. The TOMUS study was designed to look at equivalence of retropubic versus obturator slings.

Q. Do you know what products they looked at?

A. Yes.

Q. What products?

A. TVT, TVT-O, and Monarc.

Q. Do you know what general conclusions the TOMUS study reached?

A. That they were fairly equivalent.

Q. Have there been any meta-analyses performed on the TOMUS study?

MR. COMBS: Object to form.

THE WITNESS: You can't really perform a meta-analysis on the TOMUS study.

BY MR. CRONE:

Q. Let me ask it a different way. Are you aware of any -- in the medical literature of anybody performing a re-analysis of the results of the TOMUS study?

A. Well, there certainly were follow-up studies or longer-term analyses of the TOMUS data.

Q. Prior to the TOMUS study being conducted, was there a paper published in the medical literature explaining the need for the TOMUS study?

A. Well, the UITN talked about the need for the TOMUS study to compare the two approaches to see if there was a difference.

Q. And was that study called TOMUS: Design and Methodology published in 2008? Does that seem familiar?

A. That's -- that was a published publication to describe how the study was performed.

Q. Were you involved in drafting that?

A. I was on the TOMUS committee -- or I mean I'm on the urinary treatment -- the UITN, I was a founding member of that, and I was involved in designing the TOMUS study.

Q. Okay. So in that 2008 paper titled Design and Methodology, you would agree with the statement in there that said: "There are currently no adequately powered trials with sufficient length of follow-up comparing the efficacy or safety of the transobturator and retropubic MUS"?

MR. COMBS: Can one of you two repeat that question?

MR. CRONE: Sure. I'll repeat it.

BY MR. CRONE:

Q. So as a basis for the need for the TOMUS study and the Design and Methodology paper published in 2008 by the UITN, would you agree with the statement that: "There are no current" -- "There are currently no adequately powered trials with sufficient length of follow-up comparing the efficacy or safety of the transobturator and retropubic MUS"?

A. If you don't mind, can I look at the paper with that sentence and just see what context it's in in that paragraph?

Q. Unfortunately, I can't find it in the study and will run short on time. So let me just ask the question simpler.

In 2008 did you hold the opinion that more studies were needed on the safety and efficacy of the transobturator and retropubic approaches to SUI repair?

A. Well, I would say as a UITN investigator, we're constantly investigating, trying to figure out what sort of treatments were best for urinary incontinence, stress urinary incontinence, and we tried to add to the literature comparing different treatments.

You know, the literature really is -- for this particular procedure is huge. There are probably over 2,000 articles published for TVT, TVT-O-type procedures. What we tried to add to the literature was a large randomized controlled trial which adds to the smaller trials that had been done before the TOMUS study, and that was to try to increase our knowledge of the two procedures to see if they were equivalent.

Q. But in 2008, before that large randomized controlled trial performed by UITN did you believe that there were -- there were not at the time, 2008, adequately powered trials to study safety and efficacy of the midurethral sling procedures available at the time?

A. Yeah, we performed the TOMUS study through an RFA from the NIH to look at treatments for urinary incontinence, which included mesh as well as non-mesh treatments. And that's why our first study was with Burch and fascial sling. Our second study was with the mesh slings. The idea was to add to the medical literature a large randomized controlled trial that was very robust to try to test the theory of whether these procedures were equal or not.

And as part of that study, one of the

things we looked at were adverse events to try to decide -- or actually to see what adverse events occurred with a large group of treating physicians. I believe there was 53, something like that. And that's what we tried to do was to add literature to the medical science and literature at that time regarding those procedures.

Q. And I understand that portion of your answer, but the question I'm asking is much more specific.

So at the time, 2008, before the UITN randomized controlled study was performed, was one of the reasons that UITN wanted to perform that procedure due to the fact that there weren't adequately powered trials on the SUI products?

MR. COMBS: Object to form.

THE WITNESS: Well, we powered our trial to answer a specific question regarding this. There were a significant number of trials in the medical literature performed by doctors from all over the world as well as registries for the procedure. And just like any other procedure, we're always looking and testing hypotheses to see if there's something better or how we're doing. That's what it was designed to do.

We felt that our study answered another question in the performance of these procedures and that, if you will, the procedures were equivalent.

BY MR. CRONE:

Q. And so were those prior --

A. Relatively equivalent.

Q. Were those prior trials or studies adequately powered?

MR. COMBS: Object to form.

THE WITNESS: I would have to look at the studies. But, I mean, we're talking about 2008, which is eight years ago, so I don't want to misspeak and say there was something or wasn't something prior to 2008. But certainly in 2008, what we did added to the medical literature.

BY MR. CRONE:

Q. Well, you're a founding member of UITN, correct?

A. That's correct.

Q. So this 2008 paper that came out, you would have reviewed it?

A. Yes.

Q. And if you didn't agree with an opinion expressed in it, you would have expressed your disagreement?

A. We reviewed the paper as a group and came to an agreement of what to publish, yes.

Q. Okay. The same 2008 paper also says: "New surgical therapies for the treatment of stress urinary incontinence are developed and offered as a standard of care without adequate scientific evaluation of their effectiveness or safety."

Do you agree with that statement as of 2008?

A. Again, I'd like to look at the paper to see what the context of that sentence --

Q. Well, let's set the paper aside. In 2008, did you think that new surgical treatments for SUI were being introduced into the marketplace without adequate scientific evaluation of their safety or efficacy?

MR. COMBS: Object to form.

THE WITNESS: Well, I think that the procedures certainly had studies -- I mean, in this paper, we're talking about TVT, TVT-O, and Monarc. And we're talking about procedures that had been done before. And subsequently some of those products have been removed from the market. And certainly they had some problems that weren't known at the time of their introduction. And as surgeons

used these products, such as ObTape, Gore-Tex, we found problems with it and they were removed from the market.

BY MR. CRONE:

Q. When is the appropriate time to investigate for problems with a product? Let's take the TVT product specifically. Prior to introduction to the marketplace or after?

MR. COMBS: Object to form.

THE WITNESS: In general, products, drugs, medical treatments have to be tested in patients to figure out whether they can be used in patients. So you would try the product in a clinical trial, if you will, where you have a hypothesis and you test it as far as the treatment goes. Some products are comparable to previous products and may be used on the market without going through a clinical trial like that.

BY MR. CRONE:

Q. Okay.

A. Although, I mean, everything is really looked at.

Q. And so if I proffer to you that in 2008 the UITN thought SUI products were being introduced into the marketplace, specifically the TVT, TVT-O,

and the Monarc, without adequate prior scientific evaluation of their effectiveness or safety, do you agree with the UITN's position?

MR. COMBS: Object to form and foundation.

THE WITNESS: Well, first, as I've already said, I was part of the UITN.

BY MR. CRONE:

Q. That's correct.

A. So I do agree with the UITN. We felt at the time that the best and the safest products at the time were the retropubic sling -- that was TVT -- the obturator sling -- that was TVT-O -- and the Monarc sling -- that was an obturator sling as well -- were the products that we would test.

The UITN was made up of 53 physicians, the majority of which were fellowship trained in pelvic floor procedures and medical treatment of patients. Half were urogynecologists and half were gynecologists who came into the room with a lot of different ideas about how to treat patients with stress urinary incontinence.

We looked at the different procedures that were available to patients and decided what areas that we needed to try to investigate to add to the literature and improve the treatment of urinary

incontinence. For that reason, we started with the more historical procedures which were non-mesh -- that's the fascial sling and the Burch colposuspension -- because these were two procedures that historically had been done for -- well, the Burch for probably around 50 years and the sling in some form for a hundred years.

And we didn't feel that those -- that those two procedures had been adequately investigated for outcomes, adverse events, and treatments of women. So then we moved to -- once we did that to establish a baseline, we moved to the fascial sling, which is the TVT and TVT-O, which had a significant body of literature at the time, but we felt that the size of our study and the power of our study would show that -- I don't mean show. What I mean is we wanted to try to figure out whether the procedures were equivalent and then look at adverse events and problems that may occur.

Q. Okay. If I can -- I want to stop there and ask a question.

A. Oh.

Q. And so the study ultimately showed that they were equivalent?

A. Relatively.

Q. Relatively. And --

A. I mean, there's some differences. There's -- the nature of the procedures are different, so the adverse events would be a little different.

Q. Sure. But I mean, when you say "equivalent," do you mean in terms of safety, efficacy, adverse events? What type of equivalence are you referring to?

A. Well, I think all those: safety, efficacy. The adverse events, again, are different. The TOMUS group came out with a paper on the adverse events that occurred during TOMUS, and that information is incorporated in the Schimpf meta-analysis --

Q. Sure.

A. -- for adverse events.

Q. Do you know a Dr. Linda Brubaker?

A. Yes.

Q. What is your opinion of Dr. Linda Brubaker's professional abilities as a medical doctor?

A. I have a very high opinion of Dr. Brubaker.

Q. Are you aware of a -- of a paper she published titled Adverse Events over Two Years After

Retropubic or Transobturator Midurethral Sling Surgery: Findings From The TOMUS Study?

A. I am aware of that paper.

Q. It's on your reliance list, isn't it?

A. I believe it is.

Q. Okay. In that -- in Dr. Brubaker's paper, she concludes that adverse events are common after midurethral sling implants after looking at data from the TOMUS study. Do you agree with that conclusion?

A. Again, I'd like to look at the paper to see exactly the context of that sentence and the paragraph that it's written.

Q. Well, you're aware of the results of the TOMUS study?

A. Yes.

Q. You cite to them in your expert report, correct?

A. Yes.

Q. So do you not know enough about the TOMUS study to give an opinion today as to whether or not adverse events are common after MUS procedures?

MR. COMBS: Object to form.

THE WITNESS: Well, I think the better way to answer that question would be there are adverse

events that occur after either the TVT or the TVT-O or the Monarc procedure. And by common, that means all the different adverse events that can occur. And I think that it's probably more helpful for me to look at the -- how often they occur and what the -- what the adverse event is.

BY MR. CRONE:

Q. Dr. Brubaker also says: "Over a period of 24 months, 42 percent of all study participants experienced at least one adverse event, including 12 percent that experienced at least one serious adverse event."

Do you disagree with that conclusion?

A. Well, that was a conclusion based on all the adverse events that they looked at. Some of the nonserious adverse events could be things like urinary tract infections or some pain postoperatively which resolves, which we know with every procedure you get some postoperative pain. There are some more serious adverse events that are events that will resolve as the patient recovers.

So to -- I think really that you need to look at the paper and look at the adverse events that you're talking about when you make that statement -- a blanket statement like that.

Q. Well, Dr. Brubaker said that 12 percent of the 42 percent of all study participants had experienced serious adverse events. So she's saying 42 percent experienced adverse events. 12 percent of those experienced serious adverse events. Do you agree with that conclusion?

MR. COMBS: Yeah, Dr. Johnson, you've got that paper in your med lit binder if you want to look at it. It's at well-powered RCT's tab 3.

BY MR. CRONE:

Q. And while you're looking for that in your notebook, Dr. Johnson, the serious adverse events were defined in the TOMUS study, weren't they?

A. Yes.

Q. Okay. To help speed it along, I can direct you to page 3 under results, first paragraph, third full sentence that starts: "Over a period of 24 months." That's what I'm looking at there.

A. Page 3?

Q. Page 3, correct.

A. And which paragraph are you at?

Q. You know, we have different page numbers, so that's not -- it's under the results. It's near the beginning. It's under a heading called results.

MR. COMBS: It's page 4, right here

(indicating).

MR. CRONE: Thanks, Phil.

THE WITNESS: Well, in this paper, they describe -- they classify the serious adverse events versus all adverse events. And, again, there were -- you know, there was an incidence of adverse events, but the incidence of each adverse event was really low. And a lot of these adverse events are events that you can see with any surgical procedure, so they're not specific to a mesh procedure --

BY MR. CRONE:

Q. Well, only --

A. -- not all of them.

Q. Well, only mesh procedures were involved in the TOMUS study, though, correct?

A. Right, but the TOMUS procedures are surgical procedures of the pelvic floor. So these adverse events occur with any procedure for the treatment of stress incontinence.

Q. Sure. But the TOMUS study only looked at procedures involving TVT, TVT-O, and Monarc, correct? I mean, the TOMUS study didn't study all pelvic floor procedures?

A. No, but they looked at adverse events that occur with all pelvic floor procedures.

Q. I don't understand, actually.

A. Okay.

Q. I thought the TOMUS study looked at the TVT, the TVT-O, and Monarc procedures and collected data therefrom.

A. They did. We -- the adverse events that you look at are adverse events that can occur with any surgical procedure. And maybe I could give you an example --

Q. I think that would help.

A. -- that may clarify it for you.

So, for example, pulmonary embolus occurs with any surgical procedure, postoperative bleeding --

Q. Sure. Let me stop you there.

But the data that was collected from the TOMUS study didn't look at any other procedures, correct? So if a pulmonary embolism occurred in a heart surgery, it's not even collected in the data in the TOMUS study; is that fair?

A. No. No, it's not fair. Just looking at the list of serious adverse events that were collected in the TOMUS study, these are -- a lot of these are events or adverse events that can occur in any surgical procedure. And that was one of the

reasons that we looked at this, is to see if the rate of occurrence is similar to other procedures.

Q. Sure. Sure. So you're comparing those rates, but the data collected from the TOMUS procedure -- let's just -- let's just ask a few specific questions.

In the TOMUS study, no heart procedures were performed, correct?

MR. COMBS: I didn't hear your question.

BY MR. CRONE:

Q. No procedures involving the heart were performed in the TOMUS trial?

A. That's correct.

Q. Okay. And, in fact, the only procedures that were performed in that randomized controlled trial were procedures relating to TVT implantation, TVT-O implantation, and Monarc implantation, correct?

A. For the slings that were --

Q. That's correct.

A. Just for the slings.

Q. And so any data regarding adverse events and serious adverse events from those procedures came from naturally a TVT procedure, a TVT-O procedure, or a Monarc procedure, correct? I'm not

talking about what the data is being compared to. I'm talking about the data from those procedures performed in the TOMUS study.

A. Yeah, so a lot of these adverse events were adverse events that are known to occur with any surgery.

Q. Sure.

A. And there are some adverse events in here that are specific for mesh procedures -- sling procedures such as TVT or TVT-O, but not all the adverse events are specific for TVT, TVT-O. But in the study, they looked at all the adverse events that occurred whether they're specific for TVT-O, TVT, or not.

Q. Yeah, that makes sense. So let's just -- let me give you a hypothetical.

Let's say Dr. Brubaker looks at the results from the TOMUS study and she sees three bladder perforations occurred among all trial participants. That would mean those three bladder perforations occurred in either a TVT procedure, a TVT-O procedure, or a Monarc procedure, correct?

A. In this study, yes.

Q. Okay. And so you have no reason, then, to disagree with Dr. Brubaker's conclusions in her

paper that we're looking at now and discussing now?

A. Well, again, when she's talking about common, the majority of the adverse events that occurred were adverse events that can occur with any procedure, and because of that, they occurred with this procedure, if that --

Q. Yeah, I'll be more specific. I think that will be more helpful.

So you don't disagree when she says 253 out of the 597 study participants experienced at least one adverse event?

A. If you look at the serious adverse events and the adverse events data, that's the percentage, but, again, the percentage is not regarding adverse events that are specific for TVT, TVT-O. And the majority of the adverse events occurred in the less serious category, which are not specific.

Q. But you agree that 253 adverse events occurred?

A. As listed in the SAEs and the AEs data table.

Q. And that would constitute 42 percent of the study participants, correct? I can get a calculator out if you want to check her math.

A. No. That's what was reported for adverse

events, which included all adverse events, serious and nonserious.

Q. And so, then, that would make adverse events common among these procedures. Do you agree with that?

MR. COMBS: Object to form.

BY MR. CRONE:

Q. I'll be more specific.

As adverse events are defined in the study, if they occur in 42 percent of the procedures performed in the study, that would mean adverse events are common. That's Dr. Brubaker's conclusion. I'm asking if you agree with that.

A. I agree with that in respect to the adverse events as described. And the adverse events that are described, the majority of them are adverse events that can occur with any surgical procedure, so they're not -- I just want to make it clear that we're not talking about specific adverse events to the mesh slings. It could include Burch, pubovaginal. A lot of these adverse events occur with all different procedures.

Q. Sure. I think what you're saying -- and correct me if I'm wrong -- is that these adverse events aren't unique to the mesh slings, they can

happen with other procedures; is that fair?

A. That's correct.

Q. Okay.

(A discussion was held off the record.)

(A recess was taken.)

BY MR. CRONE:

Q. Dr. Johnson, could you turn to page 11 of your expert report, which is Exhibit 2. The very last paragraph, first sentence reads: "TVT was introduced in the United States by Ethicon in 1998 after receiving 510 clearance by the FDA."

Do you see that sentence?

A. Yes.

Q. What is 510 clearance -- or excuse me -- 510(k) clearance?

A. I'm not an expert on government forms, but my general understanding is that's what you go through with the FDA to introduce a product to the market.

Q. Okay. So you don't have any experience in assisting medical device manufacturers with obtaining 510(k) clearance?

A. I don't.

Q. Let's skip to page 13, the first full paragraph that starts with: "Since 2000" -- I'll

read the first sentence -- the TVT procedure has been rapidly accepted and has become the gold standard for treatment of stress urinary incontinence."

Do you see that sentence?

A. I do.

Q. What does gold standard mean?

A. That would be the most commonly performed procedure for treatment of urinary incontinence or the most widely accepted common treatment.

Q. So if there's treatment for SUI -- and in this case, we're referring to the TVT treatment -- if it's the most common or the most widely accepted, then it's the gold standard?

A. It's the most commonly performed procedure in the world, TVT is.

Q. So that makes it the gold standard?

A. I think so.

Q. Okay. Any other factors that would make a procedure gold standard or not?

A. Well, I think this procedure was looked at where they compared it to -- and this would include TVT, TVT-O procedures. So they looked at --

Q. I'm only interested, just so you know, in the TVT procedure.

A. Right.
Q. So --
A. I mean, but we just talked about that the TOMUS compared the two and they were relatively equivalent. That's the only reason I bring that up.
Q. I understand.
A. But I understand.
So it's the most commonly performed procedure for stress incontinence in the world. It's been approved by -- or endorsed by all professional organizations that look at pelvic floor treatment. It's the most studied procedure probably in history regarding treatment of urinary incontinence.
Q. And what's your basis for that opinion, that it's the most studied procedure in history for the treatment of urinary incontinence?
A. Well, there's over 2,000 studies that have been -- or are in the literature regarding --
Q. Are those all listed in your reliance report?
A. I don't know that there's 2,000 listed in there, but that's my reading of historical perspective of treatment of urinary incontinence.
Q. How many studies are there just on the

TVT? Or let's broaden that a little bit. At least looking at -- how many studies are there that look at the TVT's safety as a primary end point?

MR. COMBS: Object to form.

THE WITNESS: Well, I talk about in here that there's more than 100 randomized controlled trials. I don't think that I can give you an exact number on that, but most randomized controlled trials would look at adverse outcomes of a procedure.

BY MR. CRONE:

Q. But trials have a primary objective usually, correct?

A. They do.

Q. And then they may have secondary objectives; is that your understanding?

A. Much as the adverse event paper for TOMUS was secondary.

Q. Sure. Sure.

And so how many TVT studies, if you know, studied TVT with safety as the primary end point or outcome for the study?

MR. COMBS: Object to form.

THE WITNESS: I can't -- I can't answer that. I don't know the answer to that question.

BY MR. CRONE:

Q. Do you know --

A. I would say most studies look at adverse outcomes.

Q. But not as a primary outcome?

A. Well, you know, usually when you're -- usually when you're doing a study, you're looking at the outcome that you expect for treatment --

Q. So you're looking at --

A. -- and then associated with that would be adverse outcomes.

Q. And I didn't mean to interrupt. I'm sorry.

So you're looking primarily at subjective and objective cure rates, correct, as a primary outcome?

A. When you're performing the procedure. And then associated with that would be adverse outcomes.

Q. Okay. So you're not aware -- of these 100 studies on TVT that you cite here, you're not aware if even a single one looked at safety as a primary outcome rather than objective and subjective cure rates?

MR. COMBS: Object to form.

THE WITNESS: Well, I think just the way

that we perform these trials in the literature, we look for the outcome of treatment. And then with that, what you would call a secondary would be adverse outcomes that occur with that treatment.

But generally, we wouldn't design it the other way around. But you're still looking at the same questions if you reverse those, if you will.

BY MR. CRONE:

Q. Okay. I understand your answer.

Are you aware of two societies, AUGS and SUFU?

A. I am.

Q. Okay. And you know what those acronyms stand for --

A. Yes.

Q. -- AUGS and SUFU?

In your expert opinion, you cite their position statement on TVT as basis for your ultimate conclusion that TVT is safe; is that correct?

MR. COMBS: Object to form.

BY MR. CRONE:

Q. And I can direct you to the bottom of page 14 of your expert report. You also cite to some other societies. I'm just asking about AUGS and SUFU specifically.

And I'm not asking you to actually look at the position statement, just the bottom of page 14 of your expert report. I'm asking you if the purpose of your citation to AUGS and SUFU is that their statements support your conclusions in this expert report that the TVT is a safe product.

A. They do.

Q. Okay. Who funds the operations of AUGS?

A. I just know that I pay dues as a member. I would assume that that's -- I'm not aware of the financials.

Q. The same with SUFU?

A. Well, I'm not a member of SUFU, but I --

Q. A member of AUGS?

A. -- assume it's the same.

Q. Do you know who drafted the AUGS statement?

A. Yes.

Q. Do you know who drafted the SUFU statement?

MR. COMBS: Object to the form.

BY MR. CRONE:

Q. And just to be clear, I'm referring to the statements that you cite in your expert report. Not any statement drafted by AUGS, just the ones you

cite.

A. Each statement has the drafters listed at the end.

Q. Okay. If those drafters were all mesh manufacturer consultants, would it change your opinion as to the objectivity of those statements?

MR. COMBS: Object to form and foundation.

THE WITNESS: My reading of the statements is that they're based on the medical literature.

BY MR. CRONE:

Q. Sure. And that's not my question. My question is if you learn that all of the -- that the drafters of those statements were all consultants for mesh manufacturers, would you question their objectivity?

MR. COMBS: Object to form and foundation.

THE WITNESS: I think what I would do is read the statement and see if they were based on the medical literature, such as --

BY MR. CRONE:

Q. But you've already read the statements.

A. Yes, I have.

Q. And we already know that you agree with the conclusions in those statements. I'm asking if you found out -- if I just proffer to you today that

the authors of those statements are all mesh manufacturer consultants, would that lead you to question their objectivity in drafting those statements?

A. Well, the -- each statement is provided with the medical literature that it's based on, which is not -- which is what is used to make those conclusions. And I'm familiar with this literature. And that's why I agree with it regardless of what the authors do with any company that they work with. I think that the -- this is a statement that's not based on one person's opinion.

Q. Well, if you author a medical article or conduct a trial, something that's going to be published, and you had a potential conflict of interest, you would disclose that, wouldn't you?

A. I would disclose that, yes.

Q. And was there any sort of disclosure in the AUGS and SUFU statements about potential conflicts of interest?

A. Not that I'm aware of.

Q. Is it your opinion that the -- well, let's back up.

The TVT product uses polypropylene mesh, correct?

A. Yes.
Q. Is it your opinion that that mesh is lightweight?
A. Yes.
Q. Do you know who Dr. Mang Chen is?
A. No.
Q. Do you know who Dr. Brigette Hellhammer is?
A. No.
Q. If I told you that she was an Ethicon employee and that on September 1st, 2013 in a deposition she stated that the TVT mesh is heavyweight, would you disagree with that?
MR. COMBS: Object to form.
THE WITNESS: I'd have to look at the paper and see what you're talking about.
BY MR. CRONE:
Q. She stated that the TVT mesh is heavyweight. Do you disagree with her?
A. I'd have to look and see -- I don't know what you're referring to or what sort of --
Q. Well, you just testified that the TVT mesh is lightweight. What's the basis for that opinion?
A. That's the description of the mesh.
Q. Okay. So if an Ethicon doctor said it was

heavyweight, why would you disagree with that conclusion?

A. I don't know why they said it.

Q. They were asked is it heavyweight or lightweight. They said heavyweight. Would you disagree?

A. I don't know what they were comparing it to.

Q. You've opined that the IFU for the TVT was adequate; is that correct?

A. Yes.

Q. And that's prior to the 2015 IFU change; is that correct?

A. Yes.

Q. And is it your opinion that that IFU disclosed all potential risks --

MR. COMBS: Object to form.

BY MR. CRONE:

Q. -- associated with the TVT procedure and product?

MR. COMBS: Sorry about that. Object to form. I interrupted the question.

MR. CRONE: That's okay.

THE WITNESS: I'm sorry. I --

BY MR. CRONE:

Q. In reading your expert report, I understood it to say that you hold the opinion that the TVT IFU prior to the 2015 change was adequate because it disclosed all risks associated with the product; is that correct?

MR. COMBS: Object to form.

THE WITNESS: I think it was adequate.

BY MR. CRONE:

Q. And why was it adequate?

A. It disclosed the major known risks.

Q. What if it failed to disclose risks that were known to Ethicon, would it still be adequate?

MR. COMBS: Object to form.

THE WITNESS: I would have to look at that and compare the two.

BY MR. CRONE:

Q. Okay. So if Ethicon knew that the -- that the TVT was subject to degradation and it's not on that IFU, would the IFU still be adequate?

MR. COMBS: Objection to the form and foundation.

THE WITNESS: I've never seen degradation in a patient.

BY MR. CRONE:

Q. I know you've never seen degradation, but if that risk was known to Ethicon and it was not on that IFU, would the IFU still be adequate?

A. I would have to see evidence that degradation was significant.

Q. The same question for particle loss.

A. I would have to see medical evidence that particle loss was significant.

Q. Same question for contraction.

A. I would have to see medical evidence that contraction was significant.

Q. Same question for recurrent urinary tract infections.

A. Recurrent urinary tract infections occur with all pelvic floor surgeries, so I would have to see medical evidence that that was significant. That's a known risk of all surgeries.

Q. But it's not on the IFU, the TVT IFU?

MR. COMBS: Object to form.

THE WITNESS: Again, it's a known risk of all surgeries.

BY MR. CRONE:

Q. How about dyspareunia?

A. A known risk of all pelvic floor

surgeries.

Q. So should dyspareunia have been listed on the IFU?

A. Well, that's a general, known complication of all pelvic floor surgeries.

Q. There's nothing unique about the TVT product that could cause dyspareunia?

A. The TVT product is a pelvic floor surgery just like a pubovaginal sling, Burch, anterior/posterior repair, vaginal hysterectomy. All of these things cause dyspareunia.

Q. Are all of the potential complications listed in the IFU complications that could occur in any pelvic floor surgery?

A. No.

Q. Which ones aren't?

A. Complications specific to the mesh.

Q. So exposure?

A. Yes. Well, I should say exposure of mesh, because you can have exposure of sutures from a Burch colposuspension or you can have exposure of a biologic material used for a sling. So they're different, but they're not -- the mesh exposure is specific for mesh exposure.

Q. Sure, but the IFU then also lists

transitory local irritation at the wound site. Couldn't that occur with any pelvic floor surgery?

A. Yes.

Q. So if that's listed on the IFU, wouldn't it also be appropriate to list recurrent urinary tract infections?

MR. COMBS: Object to form.

THE WITNESS: Again, it's not specific. It wouldn't be -- it's not specific for a mesh procedure, but it's something that can occur with any pelvic floor surgery, which a mesh procedure is. So it wouldn't be wrong to list it.

BY MR. CRONE:

Q. And so then it also wouldn't be wrong to list dyspareunia?

MR. COMBS: Object to form.

THE WITNESS: You could list that.

BY MR. CRONE:

Q. Sure. And you could list recurrent UTIs?

A. Well, again, that's probably the most common adverse event with pelvic floor surgeries. It occurs with that as well as all other surgeries.

Q. You could list permanent pelvic pain?

A. Pelvic pain occurs with all pelvic floor surgeries. I mean, not in everybody, but it is a

known risk.

Q. You can list obstruction?

A. That's a known risk of a sling surgery or a colposuspension whether it's with mesh or without.

Q. Have you ever explanted a TVT?

A. I have.

Q. Okay. Have you ever had a pathology report done on any of the explants?

A. Everything that I take out of a patient I send to pathology for examination, I mean, to the best of my ability.

Q. And how many mesh explant -- TVT explant procedures have you performed?

MR. COMBS: Could you -- I didn't pay enough attention to the question. Can you just read that back to me?

(Pending question read.)

MR. COMBS: Thank you.

THE WITNESS: I don't know that I could give you a specific number because I've taken out all types of mesh products, which includes TVT as well as other products, obturator slings, so --

BY MR. CRONE:

Q. Well, let's lump them all together.

A. Okay. I can be sure it's over, I think,

50 to 60.

Q. And of those 50 to 60, did you conduct your own evaluation of the mesh ever or did you send it off to pathology when you could?

A. When I remove it, usually it's placed informal and then sent to pathology. I mean, I look at it to make sure that it's mesh and not --

Q. Sure.

A. -- so that I know what I've taken out. I don't do a pathologic examination.

Q. Sure. So you look at it with your eyes, but you don't put it under a microscope; is that fair?

A. That's fair.

Q. Okay. Are you an expert in biofilm creation?

A. I'm not.

Q. Okay. Are you a pathologist?

A. No, I'm not.

Q. Are you a chemist?

A. I am not.

Q. Any expertise in polymers?

A. No.

Q. Toxicology?

A. No.

Q. Radiology?
A. What do you mean by that?
Q. Are you a radiologist?
A. I'm not a radiologist.
Q. Engineer of any type?
A. No.
Q. Any expertise in polypropylene specifically?
MR. COMBS: Object to form.
THE WITNESS: Only as a physician that has used polypropylene mesh and polypropylene suture extensively.
BY MR. CRONE:
Q. Okay. Do you hold the opinion that the TVT product does not cause a foreign body reaction?
A. I would say one of the reasons that we use polypropylene mesh, which is TVT, and polypropylene suture is that there's minimal reaction in the body.
Q. Over the long term?
A. Yes.
Q. Okay. Fraying and particle loss, are you of the opinion on whether or not those occur with TVT?
A. I'm not exactly sure what you mean by fraying. Particle loss I have read about. But I

don't believe that particle loss or fraying are significant in my practice as far as medical outcome.

Q. If I told you that on your reliance list you list Ethicon company documents in which Ethicon doctors admit that fraying occurs, that particle loss occurs --

MR. CRONE: Counsel, forgive me for the compound nature of this question. I'm just trying to finish this up.

BY MR. CRONE:

Q. -- would that change your opinion if you -- I know you didn't review all those documents. If you reviewed those documents, might that change your opinions in this report?

MR. COMBS: Objection to form and foundation.

THE WITNESS: If I felt there was reliable medical data that showed that it was significant or had a consequence.

BY MR. CRONE:

Q. Are you going to review those Ethicon company documents?

A. Again, I would like to see medical scientific evidence of the significance.

Q. I mean, those were already provided to you. So I'm proffering to you now that those documents disagree with your conclusions and asking if you're going to review those.

A. Well, I would say if you're saying that, I probably should review them and look at them, see if I agree with that statement.

Q. And then you're open to the possibility that your opinion may change?

MR. COMBS: All right. We have to be at two hours now.

MR. CRONE: Can he just answer that question and then that will be it?

THE WITNESS: Of course I would look at any medical data and make an opinion of that data.

MR. CRONE: Okay. Thank you, Doctor.

THE WITNESS: And can I just clarify one thing?

BY MR. CRONE:

Q. I won't tell you no.

A. When we were talking about disclosures with the statements, I was thinking back to the question that you asked me about if there was a document about consulting for Ethicon as late as 2008. And just as I'm thinking about that through

my mind, I know that I filled out disclosures for articles for the New England Journal of Medicine, and I would have listed that.

But I don't know the amounts of any -- off the top of my head, as it was eight years ago, the amount that I listed as a proctor for Ethicon. But I don't think that it was a large amount. But I just don't know -- I know that I've disclosed that, but I don't know what the amount is. I don't want you to -- I don't want to imply to you that I know that amount, because I don't.

Q. Yeah, I think I understand. So you would have disclosed that for the purpose of disclosing any potential conflict of interest, is that what that's about?

A. Yeah. I just want to make sure that I haven't misstated something about a consultant --

Q. Oh, sure.

A. -- thing where I really didn't do very much and I can't -- I can't completely recall. But I do know that I filled out disclosures before.

Q. Okay. Understood.

MR. CRONE: Thank you.

(A discussion was held off the record.)

MR. COMBS: Okay. No questions.

(A discussion was held off the record.)

THE WITNESS: Rustan versus Cooper.

(Off the record at 11:02 a.m.)

CERTIFICATE OF NOTARY PUBLIC

I, Samara J. Zink, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me to testify to the truth, the whole truth, and nothing but the truth concerning the matters in this case.

I further certify that the foregoing transcript is a true and correct transcript of my original stenographic notes.

I further certify that I am neither attorney or counsel, nor related to or employed by any of the parties to the action in which this deposition is taken; and furthermore, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

_____

Samara J. Zink
Notary Public in and for the
State of Maryland

My commission expires: February 28, 2017

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

HARRY W. JOHNSON, JR., M.D. DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires:_____

_____
Notary Public

LAWYER'S NOTES

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